UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,223	01/24/2001	Raoul E. Benveniste	015280196310	2782

20350 7590 11/18/2002

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
PARKIN, JEFFREY S	
ART UNIT	PAPER NUMBER
1648	9

DATE MAILED: 11/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES DEPARTMENT OF COMMERCE
Pat nt and Trademark Office
COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

DEA/FCE-1994

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	9

DATE MAILED:

Please find below a communication from the EXAMINER in charge of this application
Commissioner of Patents

1. The communication filed on 03 September, 2002, is non-responsive to the prior Office action mailed 29 July, 2002. Applicants failed to clearly and unambiguously respond to the restriction requirement set forth in said Office action. Applicants responded by electing Group VI (claims 17, 18, and 20) with traverse but also introduced additional new claims 26-39, which are purportedly directed toward the elected invention. The addition of these claims requires further restriction vis-à-vis the originally identified and elected group.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

a. Group I, claim(s) 17, 18, 20, 26, 27, 36, and 37, drawn to a **method of immunizing** a human against HIV infection employing an **attenuated HIV** carrying a ***nef*-deletion**, classified in class 435, subclass 236, and class 424, subclasses 188.1 and 208.1.

b. Group II, claim(s) 17, 18, 20, 28-30, 36, and 37, drawn to a **method of immunizing** a human against HIV infection employing an HIV **Env subunit immunogen**, classified in class 424, subclasses 188.1 and 208.1, and class 530, subclass 350.

c. Group III, claim(s) 17, 18, 20, 31-33, and 35-37, drawn to a **method of immunizing** a human against HIV infection employing an **inactivated HIV** carrying a **gag-deletion**, classified in class 435, subclass 236.

d. Group IV, claim(s) 17, 18, 20, 31, 34, 36, and 37, drawn to a **method of immunizing** a human against HIV infection employing a **betapropiolactone inactivated virus**, classified in class 435, subclass 238.

e. Group V, claim(s) 38 and 39, drawn to a **method of inducing a cell-mediated immune response** in a human against HIV infection employing an **HIV immunogen**, classified in class 424, subclasses 188.1 and 208.1.

3. The inventions are distinct, each from the other because of the following reasons:

4. Inventions I-IV are all are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the identified methodologies employs structurally and functionally different immunogens (e.g., attenuated viruses, inactivated viruses, live viruses, subunit immunogens, etc.). Moreover, each of the identified vaccine compositions is directed toward a structurally and functionally different product. Finally, none of the products identified are required by any of the methodologies. Thus, each group identified is clearly drawn toward a different inventive concept.

5. Inventions I-IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the identified methodology of Group V is simply directed toward the induction of cell-mediated immune responses in a human subject whereas the other claims are directed toward methods of vaccination. Accordingly, different scientific reagents, protocols, and objectives are achieved by each methodology. For instance, groups I-IV are concerned with protecting a host from future infection and will raise unique issues pertaining to enablement and vaccine efficacy. However, the claims of Group V are simply directed toward methods of inducing a particular type of immune response and do not require an assessment of vaccine issues under 35 U.S.C. § 112, first paragraph. Thus, each group identified is clearly drawn toward a different inventive concept.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and require separate searches, restriction for examination purposes as indicated is proper.

7. Applicants are advised that the reply to this requirement to be complete must include an election of **one of Groups I-IV** (e.g., Group I, claims 17, 18, 20, 26, 27, 36, and 37) even though the requirement be traversed (37 C.F.R. § 1.143). The claims of Group V are directed toward a non-elected invention that is independent or distinct from the invention originally claimed as set forth *supra*. Since applicants have received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 38 and 39 are withdrawn from further consideration (refer to 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03).

8. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(I).

9. Since the response appears to be *bona fide*, applicants are given a **TIME PERIOD** of **ONE (1) MONTH** or **THIRTY (30) DAYS** from the mailing date of this notice, whichever is the longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 C.F.R. § 1.136(a).

Correspondence

10. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 O.G. 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242, (703) 305-3014, or (703) 308-4315. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

11. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 9:00 AM to 7:00 PM (Eastern Standard Time). A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner are unsuccessful, the Examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (703) 308-1122 or (703) 308-4027, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist at (703) 308-1235.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Art Unit 1648

15 November, 2002